american academy of pain management

Our Vision: No Life Limited by Pain

March 22, 2016

Representative David R. Lewis, Chair
Standing Committee on Rules, Calendar, and Operations of the House
North Carolina House of Representatives
Raleigh, North Carolina

RE: H 821 (2015), Step Therapy, and Abuse-Deterrent Opioid Analgesic Medication

Dear Representative Lewis and Members of the Committee:

On behalf of the American Academy of Pain Management, I would like to sincerely thank you for exploring step therapy reform and abuse-deterrent opioid analgesic medications (ADOs). The Academy recognizes the challenges involved in addressing two major public health crises facing our nation, namely, inadequate treatment for pain, and prescription drug abuse, and to that end, has been heavily involved in both national and state-level efforts to address both health concerns. We believe that one of the key ways we can address both public health crises is by improving the current state of pharmacy benefit management practices employed by insurers to direct which care may be affordably accessed by persons living with pain. **We believe that step therapy reform, including improved availability of ADOs, is a vital component of a comprehensive approach to addressing prescription drug abuse and improving patient care. This type of reform will help to ensure that patients are able to receive the optimal medication for their particular situation, as determined by their health care provider, and will result in an overall financial savings to the patient and the healthcare system.**

Step therapy policies, also known as "fail first" policies, are commonly used by insurance companies and other pharmacy benefit managers as a way of controlling the costs and risks associated with prescription drugs. In essence, these policies require the least expensive drug in any class to be prescribed to a patient first, even if a patient's health care provider, using their medical judgment, believes that another therapy is in the patient's best interest.

A troubling and dangerous trend is health plans' frequent denial of providers' requests for proven and effective pain treatments. Consequently, patients with serious and degenerative medical conditions are often forced to undergo an indefinite, painful, and often dangerous, process of trial and error before finally receiving the treatment originally recommended by their health care provider. In some cases, the process can cause patients' medical conditions to deteriorate, increasing the need for more expensive and invasive medical treatment in the future. What's more, patients' untreated conditions can increase the incidence of depression, non-compliance, and self-medication. Further, the step therapy process can increase the direct cost of health care due to increased hospital admissions and

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excessive use of emergency rooms. Indirect costs can include lost wages and productivity of both healthcare consumers and their caregivers.

The problems associated with step therapy are only exacerbated when applied to persons being treated for pain-related conditions, particularly when a person has already been identified as being a good candidate for an ADO. In addition to the above mentioned complications pertaining to step therapy, their exposure to non-ADOs can unnecessarily lead to exacerbation of an underlying substance use disorder, misuse of the medications by children or teens living with the patient, or diversion of the easily abused non-ADO medication to persons outside of the household. **Requiring a good candidate for an ADO medication to utilize a non-ADO medication will only exacerbate the nation's already severe issues related to prescription misuse, abuse, and overdose.**

When prescribed and monitored appropriately, most patients do well on opioid medications, and experience improvements in pain, function, and quality of life. There are instances, however, where medications are used inappropriately. The disastrous consequences of inappropriate use include a variety of adverse outcomes, including death.

The path to opioid overdoses, in many cases, begins with the misuse of prescription pain relievers. Over 70% of abusers of prescription pain relievers got them from friends or relatives. These pills are most frequently passed along by family or friends or sold on the street and then crushed, melted or otherwise altered to get a more powerful effect. However, ADOs lose their effectiveness when they are crushed or melted, making them far less desirable to those who would otherwise divert the medications for unlawful use. It is our belief that ADOs should be part of a multi-faceted approach to decreasing abuse. **Although ADOs do not prevent users from simply consuming too much of a medication, they may help reduce the public health burden of prescription opioid abuse in North Carolina by making it harder and less desirable to abuse opioid medications in common illicit and dangerous ways.**

People are prescribed ADOs, rather than non-ADOs, to treat their pain conditions for a variety of reasons: some want to prevent access to non-ADOs to the teenagers living in their home; some live with roommates; some have a history of substance use disorder (not just prescription-related, but alcohol and illicit drugs). Whatever the reason, these persons, along with their health care providers, have decided that an ADO is an appropriate medication to simultaneously manage their health condition and to protect the public safety.

It's entirely possible that, at this point, you are wondering, "With all of the risk, why would a health care provider prescribe an opioid at all? Aren't there better alternatives?" The answer depends on many factors: the patient's specific condition, available treatments, and which treatments are covered by insurance. Unfortunately, pain is severely under-researched, a problem that we are keenly aware of and are actively working to address through federal legislation which seeks funding related to chronic pain research. The current lack of research means we have a severe lack of alternative medications to treat pain. Further, insurers point to the lack of "high quality evidence" to avoid paying for alternative treatments for pain, such as acupuncture, chiropractic, massage therapy, physical therapy, occupational therapy, and more. What's more, for some patients, alternatives that do exist aren't appropriate treatment options for their particular condition (for example, patients with kidney

problems cannot take NSAIDs as an ongoing treatment). For many conditions, there are disease-specific medications available, and those medications are used when clinically indicated, but they simply do not exist for every condition or work for every person. **All persons, regardless of their unique medical condition or their financial standing, should have access to high quality and effective health care.**

It is vital that you act now to ensure appropriate access to ADOs. The Food and Drug Administration (FDA) wrote in a 2013 ADO-related guidance for drug makers that the "FDA considers the development of these products a high public health priority." Further, in February 2016 the FDA announced that they will now mandate that any new opioid go before an outside committee of experts, unless the product has abuse-deterrent properties. It is clear that the FDA has recognized the promise of these life-saving medications, but they will only live up to that promise if they are affordable to those who need them.

We have been monitoring ADO-related legislation for two years, and we are currently tracking 43 related bills across the country. After our extensive evaluation of these policies, we have determined that there are five key provisions that all great ADO legislation shares:

1. Require insurers, nonprofit health service plans, and health maintenance organizations to **provide coverage** for abuse-deterrent opioid analgesic drug products (ideally as many types of insurers as possible);
2. **Prohibit** the insurers, nonprofit health service plans, and health maintenance organizations from imposing certain limits or **cost-sharing requirements** on coverage for ADOs that are less favorable to an insured or an enrollee than the limits or cost-sharing requirements that apply to coverage for any other opioid analgesic drug product;
3. **Prohibit** the insurers, nonprofit health service plans, and health maintenance organizations from **requiring an insured or an enrollee to first use a certain drug product before providing coverage** for an ADO;
4. **Prohibit** the insurers, nonprofit health service plans, and health maintenance organizations from **increasing certain cost-sharing requirements or other out-of-pocket expenses to achieve compliance** with the above requirements, and further, prohibit the creation of a financial disincentive for a prescriber or dispenser to prescribe or dispense an ADO; and,
5. **Authorize** the insurers, nonprofit health service plans, and health maintenance organizations to utilize **prior authorization** for an abuse-deterrent opioid analgesic drug product **so long as** the prior authorization requirements are **the same as those used for non-abuse-deterrent** opioid analgesic drug products.

We applaud you for recognizing the need to investigate step therapy and abuse-deterrent formulations of opioid analgesic medication. Requiring coverage parity between ADOs and non-abuse-deterrent opioids, and thereby ensuring patient access to ADOs, is critical if we are to see the full benefits of such technologies. ADO analgesics can help reduce the number of opioid overdose deaths, but they will not be effective if no one uses them because they cannot afford them. Passage of legislation that covers

the above-mentioned areas will help to ensure that those who would benefit from ADOs will receive them and at a price they can afford. What's more, ensuring that ADOs are able to be used as a first line treatment will reduce the number of non-ADOs in circulation that have the potential to be diverted and misused.

The Academy views step therapy reform and access to affordable abuse-deterrent opioid analgesic medications as vital components of a comprehensive approach to addressing prescription drug abuse. I am happy to discuss this issue with you if necessary. Please feel free to contact me by email at kduensing@aapainmanage.org, or by telephone at 209-288-2214.

About the Academy: The American Academy of Pain Management is the premier organization for all clinicians who care for people with pain. It is the largest pain management organization in the nation and the only one that embraces, as part of its mission statement, an integrative model of care, which: is patient-centered; considers the whole person; encourages healthful lifestyle changes as part of the first line of treatment to restore wellness; is evidence-based; brings together all appropriate therapeutic approaches to reduce pain and achieve optimal health and healing; and, encourages a team approach.

Sincerely yours,

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